510(K) SUMMARY
(DATE PREPARED: MAY 15, 2012)

Device Name
Arctic Sun Hybrid ArcticGel Pad

JUL 20 2012

Manufacturer Name , Address and Contact Information
Medivance, Inc.
321 South Taylor Avenue, Suite 200
Louisville, CO 80027
Contact: Lynne Aronson, Director Regulatory Affaris
Phone: 303-926-1917
Fax: 720-880-5400

Common, Classification & Proprietary Names

Common Name:	patient temperature management system
Classification Name:	system, thermal regulating
Proprietary Name:	Arctic Sun Hybrid ArcticGel Pad
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Classification Regulation:	870.5900
Product Code:	DWJ

Predicate Devices

▪ Medivance Arctic Sun ArcticGel Pad	K010338
▪ EMCOOLS Pad	K100071

Device Description
The Arctic Sun Hybrid ArcticGel Pads are a modified version of the Arctic Sun ArcticGel Pads.

The Hybrid ArcticGel Pad is designed to operate in two different modes; Ice Gel Mode in which is the pre-frozen pads are used as standalone devices to initiate patient cooling, and Water Flow Mode in which the pads are connected to the Arctic Sun Temperature Management System which is used to control the patient at a target temperature.

These dual modes provide the opportunity for early initiation of cooling in the pre-hospital setting or the hospital emergency department followed by continued temperature management with the Arctic Sun once the ice gel is thawed.

The Hybrid ArcticGel Pads are pre-frozen in a freezer operating between -3°C and -20°C (27°F and -4°F). The release liners are removed from the hydrogel adhesive, and the frozen Hybrid ArcticGel Pads are applied to the patient's skin. Between 4 and 8 pads are applied to the patient, depending on the patient's size and patient temperature reduction required. Heat from the patient is conducted through the hydrogel and pad layers into the ice gel compartment. The heat from the skin melts the ice gel. The duration of Ice Gel Mode is approximately 60 to 90 minutes from the time of application to complete melting of the Ice Gel.

To convert to Water Flow Mode, pad lines are irreversibly snapped onto the inlet and outlet water ports of the Hybrid ArcticGel Pads. The pad line connectors are connected to the Arctic Sun fluid delivery line. Up to 6 Hybrid ArcticGel Pads may be connected to the Arctic Sun. Temperature controlled water from the Arctic Sun control module can then be circulated through the pad. The water passes through the water flow compartment, allowing heat to be transferred from the patient's skin across the hydrogel adhesive and into the circulating water.

Indications for Use

The Hybrid ArcticGel™ Pad is indicated as a standalone cooling device for the reduction of core temperature of adult patients where clinically indicated (e.g. heat stroke or hyperthermia).

Additionally, the Hybrid ActicGel™ Pad is indicated as an adjunct to patient temperature control with the Arctic Sun® Temperature Management System.

The Hybrid ArcticGel™ Pad is intended for use by health care professionals in all clinical environments, including, but not limited to in- hospital as well as EMS/transport settings.

Substantial Equivalence

The Arctic Sun Hybrid ArcticGel Pad was shown to be substantially equivalent in intended use, design, technological characteristics, materials and system features and functions to the predicate devices.

The Hybrid ArcticGel Pad and the predicated ArcticGel Pads and EMCOOLS Pads are non-invasive surface temperature management devices. The Hybrid ArcticGel Pads and the EMCOOLS Pads may be pre-frozen and used as standalone devices for use in patient temperature reduction. Additionally, the Hybrid ArcticGel Pads and the predicate ArcticGel Pads may be used in with the Artic Sun Temperature Management System for use in continuous patient temperature monitoring and control.

The Hybrid ArcticGel Pads and the predicate devices are manufactured from polymer materials that are common to many disposable medical devices, and utilize a biocompatible medical adhesive material to adhere the pads to the patient's skin. The Hybrid ArcticGel Pads and the predicate devices are of similar sizes and weights, and provide similar cooling capacities and durations.

Testing

Biocompatibility testing performed in accordance with ISO 10993-1, 10993-05 and 10993-10 demonstrated the hydrogel patient adhesive to be non-cytotoxic, non-irritating and non-sensitizing.

Comparative performance testing demonstrated that the cooling and temperature control performance of the Hybrid ArcticGel Pads is substantially equivalent to that of the predicate devices.

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Safety tests performed in the porcine skin model demonstrated that the minimum mean skin temperature remains above freezing, reaches its minimum value within the first 15 minutes after pad application, and gradually rises over the course of the 90 minute cooling treatment. The placement of the frozen Hybrid ArcticGel Pads on the pigs' skin of pigs was well-tolerated.

Conclusions

Based upon the testing and comparison to the predicate devices, the Arctic Sun Hybrid Arctic Gel Pad performs as intended and raises no new safety or effectiveness issues.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 20 2012

Medivance, Inc.
c/o Ms. Lynne Aronson
Director, Regulatory Affairs
321 South Taylor Avenue, Suite 200
Louisville, CO 80027

Re: K120849
Hybrid ArcticGel Pad
Regulation Number: 21 CFR 870.5900
Regulation Name: System, Thermal Regulating
Regulatory Class: Class II
Product Code: DWJ
Dated: May 21, 2012
Received: May 22, 2012

Dear Ms. Aronson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. S. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE (FDA FORM)

Statement of Indications for Use (FDA Form)

510(k): K120849

Device: Hybrid ArcticGel Pad

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Prescription Use X OR Over-the-Counter Use
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120849

(Optional Format 1-2-96)